

2. How Many Times Can an ANDA or § 505(b)(2) Application's Approval Date Be Delayed by 30-Month Stays?

The proposed rule offered an interpretation of the act that would limit the number of 30-month stays to only one possible stay per ANDA or 505(b)(2) application. The proposed interpretation in the proposed rule differed from our previous interpretation of the act (which allowed for multiple 30-month stays). Under our proposed interpretation, the ANDA or 505(b)(2) applicant would continue to file the appropriate certifications as required under section 505(j)(2)(A)(vii)(I) through (j)(2)(A)(vii)(IV) or section 505(b)(2)(A)(i) through (b)(2)(A)(iv) of the act. However, under the proposed interpretation in the proposed rule, the notice to the NDA holder and patent holder of the paragraph IV certification is required only when a paragraph IV certification is included in the initial ANDA or 505(b)(2) application or when such an application is amended to include, for the first time, a paragraph IV certification. Notice to the NDA holder and patent owner is one of the requirements for a 30-month stay; if the ANDA or 505(b)(2) applicant is not obliged to provide a subsequent notice to the patent owner and NDA holder, no successive 30-month stay is possible.

a. *When Must Notice Be Provided and What Is a Full Opportunity for a 30-Month Stay?* The proposed rule would require an ANDA or 505(b)(2) applicant to provide notice to NDA holders and patent owners only when the applicant files a paragraph IV certification with the initial application or amends the application to include a paragraph IV certification for the first time. If the application were amended to add additional paragraph IV certifications, no notice to the NDA holder and patent owner would be required.

(Comment 13) Several comments claimed that the lack of notice for subsequent paragraph IV certifications would delay initiation of patent litigation. To avoid this "delay," the comments suggested that, if we retained our proposed interpretation allowing only one 30-month stay per ANDA or 505(b)(2) application, we should amend the rule to:

- Give the ANDA applicant the "option" to provide voluntary notification;
- Give the ANDA applicant the "option" to provide notification and be subject to an "optional" additional 30-month stay;

• Require us to notify the NDA holder as to a subsequent paragraph IV certification.

Similarly, several comments expressed concerns that ANDA and 505(b)(2) applicants could manipulate the rule to avoid even a single 30-month stay. The comments explained that in the absence of notice for all paragraph IV certifications, there could be several scenarios in which an ANDA or 505(b)(2) applicant could take advantage of the regulations to avoid a meaningful 30-month stay under our revised interpretation. For example, an ANDA or 505(b)(2) applicant could file a paragraph IV certification on a narrow patent or a narrow patent claim and provide notice to the NDA holder and patent owner on that certification, thereby satisfying the regulatory requirements, while providing a paragraph III certification on broader patents or claims. The NDA holder or patent owner could bring a patent infringement suit within the 45 days, triggering a 30-month stay, or decide not to bring suit on the narrow claim or patent. The comments argued that, after suit was filed, or after the 45 days expired with no suit initiated, the ANDA or 505(b)(2) applicant could change the paragraph IV certification to a paragraph III. If suit had been filed, the applicant could seek dismissal of the patent infringement suit and avoid the 30-month stay. At a later date, the ANDA or 505(b)(2) applicant could change its paragraph III certification on the broader patent or claim to a paragraph IV certification, but because there had already been an opportunity for a 30-month stay, no further 30-month stay would be possible.

The comments maintained that we should not allow such manipulation and that it could be avoided by treating the new or revised certification as though it relates back to, and substitutes for, the original certification so that the notification requirements for original applications, and not those for amendments, apply. Under this suggested approach, the changed paragraph III certification would be treated as if the original application had contained the paragraph IV certification. The new certification, thus, would require notice to the NDA holder and patent owner and have the potential to trigger a 30-month stay. The comment cited § 314.94(a)(12)(viii) which relates to amended certifications to support this approach. In this instance, it was argued that there should be the opportunity for at least one 30-month stay when the ANDA or 505(b)(2) applicant "alters or amends" a patent certification for

reasons other than the listing of a patent subsequent to the filing of an ANDA.

(Response) We decline to modify the proposed rule as suggested. We conclude, however, that clarification of the proposed rule is required in the final rule to ensure that our revised interpretation allows for one full opportunity for a 30-month stay after notice of a paragraph IV certification.

Our long experience with administering the Hatch-Waxman Amendments convinces us that any regulatory scheme in this area will be complex, and that any advantage that a party can find in manipulating the regulatory program will be pursued. Despite our conviction that the final rule will substantially reduce such manipulation, we do not believe we can completely prevent attempts at "creative compliance" by the parties.

Our revised interpretation of the statute reads all three subparagraphs of section 505(j)(2)(B) of the act as a coherent whole. We believe that Congress considered the first paragraph IV certification, notice and the opportunity for a single 30-month stay, to be part of an inter-connected process. In the final rule we keep these provisions operating together, as much as possible, requiring that certifications be made and notification provided in such a way that there always will be one full opportunity for a 30-month stay.

The notice requirement in the final rule depends on whether the ANDA or 505(b)(2) application contained a paragraph IV certification before the submission of an amendment containing a paragraph IV certification. We note three potentially confusing situations concerning applicability of that principle and describe how these will be treated under the final rule.

First, an ANDA or 505(b)(2) applicant who filed a paragraph IV certification could change to a paragraph III certification after notice is given but before the 45 days for filing suit has run and before a suit is filed. In this situation, because the opportunity for a 30-month stay has not vested (the 45 days has not expired or patent litigation has not yet been initiated), under the final rule, this ANDA or 505(b)(2) application will not be considered to have ever included a paragraph IV certification. If a paragraph IV certification is submitted later, the notice obligation and one full opportunity for a 30-month stay will attach. This ensures that, consistent with the statute, for at least one paragraph IV certification, the NDA holder or patent owner has a full 45 days to determine whether to exercise the right to sue for patent infringement